Adverse Reactions with Aquamid®

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ABSTRACT

Adverse Reactions Following Injection with a Permanent Facial Filler, Polyacrylamide Hydrogel (Aquamid®) - Causes and Treatment

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BACKGROUND

Polyacrylamide hydrogel (Aquamid®), an atoxic, non-immunogenic gel of non-resorbable type, has gained widespread popularity as an injectable filler for facial augmentation.
However adverse events/complications occur, whose nature seem obscure because of negative findings on culture and pattern of foreign body response on microscopy.

Purpose of the study
To evaluate and investigate all reported adverse events following injection with Aquamid® in approximately 40,000 patients over a period of 2 years and 4 months.

Methods
A prospective study of case reports provided by injecting physicians during the period May 2001 to September 2003.

Patient material
Among 40,000 patient injected, 55 were reported having adverse events. Information from questionnaires and follow-up information from involved physicians was collected into a database.

Data collection

The data on each patient was collected into a database and contained information about

1) previous or current disease
2) previous injections or surgery at the same site
3) allergic or hereditary disorders
4) dates of injection, adverse event, treatment and follow-up
5) details regarding injection procedure, diagnostic measures and findings
6) details regarding treatment and outcome

Definitions
A related adverse event was defined as any injection site reaction which did not disappear spontaneously within 2-3 days.
Injection site nodule was clinically defined as a swelling lasting for more than 2-3 days associated with one or more of the following:

- Tingling sensation
- Redness
- Pain
- Pulsation
- Abscess or fistula formation

The identification of bacteria was performed by DNA sequencing.

CLINICAL RESULTS

- Adverse events occurring mainly in lips and nasolabial folds were reported in 55 patients.
- The time from last gel injection to debut of adverse event varied from 2-364 days with a median of 12 days.
- Almost all patients recovered on antibiotics which supports the view that infection by micro-organisms was the cause, even if it was not practically possible in all cases to detect the micro-organism.

Conclusion
Adverse events presenting clinically as nodules or swellings later than 1 week and less than 1 year after the injection of Aquamid® should be suspected as low-grade infections and be treated immediately with a broad-spectrum antibiotic in high dosage.
Steroids or NSAIDs are contraindicated.

EXECUTIVE SUMMARY

- 0,1% adverse events was found in this study.
- Low grade infection must always be suspected if reactions occur later than one week after injection.
- High dosage broad-spectrum antibiotic treatment should be started immediately.
- Steroids or NSAIDs tend to aggravate symptoms and prolong treatment time and should therefore be avoided.

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